HIT Policy Committee Meeting
Draft Transcript
May 6, 2010

Presentation

Seth Pazinski – ONC – Special Assistant
Thank you. Good morning, everyone, and welcome to this meeting of the HIT Policy Committee. Again, this is a federal advisory committee. The members of the public are listening on the phone, and there'll be an opportunity at the close of the meeting for public to make comments. I'm going to do a roll call now, so could members please indicate if you're on the phone when I call your name? David Blumenthal?

David Blumenthal – Department of HHS – National Coordinator for Health IT
Here.

Seth Pazinski – ONC – Special Assistant
Paul Tang?

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO
Here.

Seth Pazinski – ONC – Special Assistant
David Bates? Roger Baker? Christine Bechtel?

Christine Bechtel - National Partnership for Women & Families – VP
I'm here.

Seth Pazinski – ONC – Special Assistant
James Borland? Neil Calman? Richard Chapman?

Larry Wolf – Kindred Healthcare – Senior Consulting Architect
It's Larry Wolf on for Rick Chapman.

Seth Pazinski – ONC – Special Assistant
Adam Clark? Arthur Davidson?

Art Davidson - Public Health Informatics at Denver Public Health – Director
Here.

Seth Pazinski – ONC – Special Assistant
Connie Delaney? Paul Egerman?

Paul Egerman – eScription – CEO
Here.

Seth Pazinski – ONC – Special Assistant
Judith Faulkner?

Carl Dvorak – Epic Systems – EVP
Carl Dvorak here with Judy. She'll be joining us momentarily.

Seth Pazinski – ONC – Special Assistant
Gayle Harrell? Charles Kennedy? Michael Klag? David Lansky? Deven McGraw?

Deven McGraw - Center for Democracy & Technology – Director
Here.

Seth Pazinski – ONC – Special Assistant
Frank Nimek? Marc Probst?

Marc Probst – Intermountain Healthcare – CIO
Here.

Seth Pazinski – ONC – Special Assistant
Latanya Sweeney? Tony Trenkle? Commander Michael Weiner? Scott White?

Scott White – 1199 SEIU – Assistant Director & Technology Project Director
Here.

Seth Pazinski – ONC – Special Assistant
Thank you. Is there anyone else on the phone that I missed?

George Hripcsak - Dept. of Biomedical Informatics Columbia University – Chair
George Hripcsak is on the phone.

Seth Pazinski – ONC – Special Assistant
All right. With that, I'll turn it over to Dr. Blumenthal and Dr. Tang to start off the agenda.

David Blumenthal – Department of HHS – National Coordinator for Health IT
Thank you, Seth, for jumping in to Judy's shoes. They're very hard to fill in this setting. This was a call that we put together fairly rapidly because the adoption certification working group had some recommendations related to the permanent certification program, which has a separate comment period from the temporary certification program with regard to the regulation. And the comment period is closing very shortly, so we wanted to give the adoption certification working group a chance to put its recommendations before the full policy committee for consideration and ultimately submission.

I'm going to let Paul, as he so often and ably does, chair this discussion since I'm the target of the recommendations, but I do want to give one point of information before we get going. We discussed, and this is a quite different topic, but one I think that will be of interest to the committee, and we'll repeat in person when there's a greater attendance at our next in person meeting. There is a provision under the health reform law that is in Section 1561 for any of you who have the law in front of you. This one actually asks the policy committee and the standards committee to do some fairly short term work with respect to approving standards that would enable social and health service databases to communicate with one another for the purposes of supporting enrollment in health insurance through health insurance exchanges that will be created in 2014 under the law. There is, however, a very short timeframe, a 180-day timeframe for the standards and policy committees to address this issue.

Now the law was signed on March 23rd, so 180 days is now closer to probably 120 days, and this is going to be, I think, a pretty demanding, complicated task. We've asked for some additional resources to help us support the committees on this, and we will doing so. But we're also going to be forming a joint working group of the policy committee and the standards committees to address this issue. It's a little bit off the standard topic that we'd been dealing with because it asks us to look beyond the health area into social service, and social service includes such diverse services as food stamps, which is run out of the Department of Agriculture, the Women, Infant, and Children's Program, the Departments of Motor Vehicles, any place where the public has contact with the government, and where they might be given the chance to be made aware of their insurance options and rights and responsibilities.

We are trying to define the scope of the task, as we speak, but I just wanted to let you all know that this was coming at you. We've appreciated your support and hard work up to now, and we're transitioning to an added responsibility. This is absolutely typical of everything that's going on within the department right now. No matter how hard you were working before, there's more work to do now after health reform has been passed. With that introduction, I'm going to turn it over to Paul to let him chair the proceedings.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO
Thanks, David. The translation for the committee is just praising you for what great work you do … rewarding with more work. Anyway, as David mentioned, this is a discussion period for a couple proposed letters to be submitted in, in time for the NPRM related to certification or the permanent group. And there are a couple letters. One is shorter than the other, so the adoption certification workgroup has the longer letter, and then privacy and security workgroup also has an addition to that. Let me turn it over to Paul Egerman to discuss, to present the adoption and certification workgroup letter.

Paul Egerman – eScription – CEO
Yes. Thank you. It's Paul Egerman. Thank you, Dr. Tang, and Dr. Blumenthal. The adoption certification workgroup has been working on dual tracks. We've worked with patient safety and also with the certification NPRM at the same time, and I appreciate everybody accommodating the schedule and participating this morning. And I'm particularly pleased to hear from Dr. Blumenthal that it will be something else to be working on after this process.

But to talk about the permanent program in the NPRM, there are two programs. There's a temporary program that we commented on about a month ago. This is a permanent program that replaces that temporary program. And to simply start with a very general comment, I would simply say that our workgroup was extremely pleased with the structural approach that ONC is taking to certification.

We were gratified that our recommendations from last August appeared to be listened to and received favorably. And, most importantly, we were pleased at what is happening here where certification is being separated from the testing process or there's an accreditation organization. All of these things are very positive, and we'll make sure that we have the certification that's sort of objective and transparent and that people have confidence in. So we have 12 recommendations.

If you like it so much, why do you have 12 recommendations? The situation is, in the NPRM, there were a number of places where the text says that ONC was requesting public comment or requesting comments, and so we felt if they're asking for a comment, it was partly our responsibility to respond. So we actually just went through the NPRM and responded where there were requests for comments.

Some of this is very detailed, but we did put the most interesting ones first. The first question related to the elements of the surveillance process. I'm going to walk you through these very, very fast, but the

surveillance process is a process that the certification entities are supposed to do when you have an annual surveillance plan.

The question was, what are the basic elements of that plan? We brought forward three elements. One was to make sure these systems comply with the testing criteria. In other words, if they pass the test, per se, an interface specification, are they still able to operate according to that specification, natural operation.

The second one was compliance with what we called certification criteria, so this is really sort of non-software like vendor behavioral activities. This is mainly issues of labeling. Are the products labeled according to the rules? Are people making correct or inaccurate claims about the level of certification that they have and what it means?

And the third element that we've listed was, we call it an effectiveness element, but sort of like seeing the forest for the trees, which is, even though these systems pass certification and testing in the view of the purchasers, are they effective for achieving meaningful use? Can you really achieve meaningful use with these systems? We made another recommendation that there be a labeling requirement that would tell purchasers how to report or complain if they had any concerns about the certification process.

The second issue related to de-certification, the NPRM asked an interesting question. Should the National Coordinator have the authority to de-certify a product or a vendor if the National Coordinator thinks that's necessary to protect a purchaser? We said yes, under some egregious situations, we could see that that would be important to do.

The third issue relates to this thing called differential certification, which may seem like a mouthful, but it's sort of a way of saying suppose in stage one you have something like eligibility checking against a meaningful use requirement, and that requirement continues to exist for stage two, but it doesn't really change in any way. Do you have to be retested and recertified for it for stage two and possibly for stage three? We answer that by saying if you've already passed the test, if an applicant has past the test, and if the test hasn't changed, and if the software version hasn't changed, then you don't have to be tested again. That was our answer for differential certification.

The next issues relate to the accreditation organization. These are, again, a little bit technical about ongoing responsibilities. We want the accreditation organization to help track backlogs that exist. We made a comment about the period and term for the accreditor should be in place for recommendation number six, promoting participation in the permanent program. We made a comment here that's actually duplicative of our comment in the temporary program where we encouraged the ability for certification bodies to be able to be qualified, not just to do modules or complete EHRs, but also to be able to do certifications for ambulatory EHRs. We saw that as a valuable stepping-stone. We made a comment about the stark exception, which we agreed with the approach taken.

Then you see recommendation number eight relating to modules. The legal advice that we've received from ONC was we had to repeat all of our temporary recommendations as part of the permanent recommendation process if we wanted them to also apply. This recommendation about modules is one that we presented to you last month, and it really hasn't changed.

The recommendation about location of testing actually is a recommendation we made last month that we did change based on receiving new information that last month we said the primary testing location should be the certification bodies testing labs. What we learned was the current state of the art is that

almost all the testing is occurring remotely. So we simply changed this to be clear that remote location really should be the primary location for testing.

Recommendations ten about the number of standards are the same as what we did for the temporary program. Recommendation number 11 for certification clarity is very important, we think, to have a labeling program, but that is a repeat of what we presented last month, and what you approved.

Then last recommendation is sort of an interesting issue. This is an issue we suspect that ONC will receive a number of comments, in the NPRM allows the certification process to be used for other HIT systems. So an example, you could, if you had the right criteria in place, you could use it to certify, for example, PHRs if you wanted to. And we comment on that. I think other people are commenting on that too.

Our comment was, we thought actually it was good to provide that kind of flexibility in the process. There was a little bit of concern that was expressed that, gee, we didn't want to see mission creepers. The scope of certification start to change significantly from what it started to be. While we said the flexibility was good, we thought it was a good way or the opportunity also just to remind everybody of what the goals in certification were.

We also thought it was a good way to end our letter with the reminder of the goals. The goals are to focus certification on meaningful use, and to leverage certification to improve progress on privacy, security, and interoperability. And we're saying that this flexibility is good, as long as we don't lose sight of our basic goals. So that, in very rapid fire way, is a quick summary of our recommendations, again, a lot of detail, but I thought it best if I sort of ran through it like that and asked people if they have any comments or questions.

Deven McGraw - Center for Democracy & Technology – Director
This is Deven McGraw. I think, on comment 12, I think the one issue that gives me a little bit of pause is that, in the past, the voluntary certification effort that CCHIT did on PHRs was, in many ways, at least in my view, an attempt to use certification in a policy vacuum. Where we have a lot of concerns about PHRs that are not covered by HIPAA or any comprehensive privacy rules to protect the information in them, the certification piece can't accomplish that, and we still need those policies in affect there. So I certainly wouldn't want folks to take 12B, for example, to mean that we think that certification should play a greater role in privacy and security than supporting the adoption of the technical features that in fact do advance greater protection, but they can't provide policy in that vacuum.

I don't know if there's any way to get that in ten across in a simple way. I don't even know if folks agree with me on that, but that was the concern that I got in reading 12B because it's nice and short. And I think that we mean the technical pieces that advance the policies. Since we don't have the policies, there's a little bit of uncertainty about what we mean there.

Paul Egerman – eScription – CEO
Yes. Those are good points, Deven. Actually, what we did in 12B is we just sort of echoed back the exact wording that was in the NPRM for the goals of certification.

Deven McGraw - Center for Democracy & Technology – Director
Right.

Paul Egerman – eScription – CEO

The concern that you're expressing is a concern that was expressed in various forms by other people also. The comment I'd make is it's not like … this is an NPRM about the process, but it's not like certification bodies can just start certifying whatever they want. You still have to go through an entire process of ONC producing some IFR or NPRM or something that describes what he criteria is. There still would be a whole policy discussion on all of these things, so just like the very first thing, and 12B is no different than 12A. Certification bodies can't decide on their own what meaningful use is. The same is true for 12B that certification bodies can't decide on their own what privacy policies are going to be or what are the elements of interoperability. Those have to come from ONC, presumably with some policy direction behind it.

Deven McGraw - Center for Democracy & Technology – Director
That's fair.

Gayle Harrell – Florida – Former State Legislator
Paul, this is Gayle.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO
And this is Paul Tang.

Gayle Harrell – Florida – Former State Legislator
Could I make a comment?

Paul Egerman – eScription – CEO
Sure.

Gayle Harrell – Florida – Former State Legislator
I have an issue, a little bit of a concern with 12 also, more on the line of mission creep. I think when you talk, you know, if you're going to open the door to the discussion of a PHR without the kind of legislative mandate that we have to address that, for us to make any recommendation, we have no authority really to do that. And once you put something in writing in a formal letter, that speaks for us as a committee and really broadens our charge, so I think we need to be very cautious about mission creep and not … into an area that really is not within the purview of what we are charged to do. Putting it in a formal letter such as this to the Office of the National Coordinator really opens that whole door and calls into question what is our mission, and are we expanding that. And we have to be extremely cautious because when you start down that road, it's the old camel's nose under the tent kind of thing, you know, where does it stop?

Paul Egerman – eScription – CEO
Yes. Thank you, Gayle, for that comment. The situation though, I just want to make sure you understand. It's already in the NPRM. In other words, we're not introducing this as the new concept. We are commenting on something that is in the NPRM. The NPRM says that they can do this, and basically suggests that people should comment on that. What we are saying is actually consistent with what the concern that you're expressing is. What we're saying is it's fine to have that flexibility as long as you really use it to the extent that it is needed to support the certification objectives.

Gayle Harrell – Florida – Former State Legislator
What you're saying, Paul, is mission creep is within the NPRM.

Deven McGraw - Center for Democracy & Technology – Director
But it's an interpretation of statutory language, I think—this is Deven—that actually does invite them to go there because I had those very same concerns, Gayle.

Art Davidson - Public Health Informatics at Denver Public Health – Director
This is….

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO
…HIT, and by introducing category two, engage patients and families, and referring … personal health records, we've sort of already discussed this, and it is part of meaningful use.

Paul Egerman – eScription – CEO
Yes. What we're trying to say here, and maybe we need to word it a little differently, it's okay to do as long as it's related to our basic goals. But if people object, we can certainly drop the comment.

Art Davidson - Public Health Informatics at Denver Public Health – Director
This is Art. I thoroughly agree with this. We could put the restrictions and put the word improve technical progress to address Deven's concern. But the whole idea about the patient engagement, empowerment, all that depends on some mechanism to have them be engaged. I thought the PHR was part of that process at some point, and that allowing someone to certify that their PHR is CCD compliant seems to me like a reasonable step to getting them engaged.

Paul Egerman – eScription – CEO
I just want to make sure I understand what you said, Art. You're saying, if I've got it right, you're saying you like what it says here for Section 12. You just want to add the word "technical" between the "improve" and "progress".

Art Davidson - Public Health Informatics at Denver Public Health – Director
So that way … right, so that it doesn't, as Deven said, fill a policy void by just presuming that this is now going to address some policy issues.

Paul Egerman – eScription – CEO
Is that helpful to your concern, Deven?

Deven McGraw - Center for Democracy & Technology – Director
It is. It's very helpful.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO
Actually, this is—this is Paul Tang—12B is a bit of a carry over and reflection of the AHIC process in the sense of when AHIC asked CCHIT to look at PHR certification, it was restricted to this area because it really is supporting the fact that privacy and security is a wraparound for everything. And it wanted to stay away from certifying functionality per se in those days. But really supporting what we've always been saying, which is privacy and security is foundational, and particularly since PHRs are a lot outside of the HIPAA realm, then we want to just make sure. It was our poor man's way of making sure that information is protected, as part of this whole HIT adoption process.

Paul Egerman – eScription – CEO
When I use PHRs as an example, I know it shows the most controversial example. We probably wouldn't have had much discussion if I had said packs systems. But the idea is, this is what's there. The flexibility is there, and the intent though is to address the mission creep by making sure that we don't lose focus.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO
Right.

Larry Wolf – Kindred Healthcare – Senior Consulting Architect
This is Larry. I'd like to jump in with a quick observation about what we're calling mission creep here, which in fact is a fundamental policy problem that we've been struggling with from the beginning that the legislation takes two areas within healthcare to focus on, but there are many other areas within healthcare that are not addressed. And if we're really looking at providing coordinated care, continuity of care, and all of those points feed patient record repositories of some kind, that the actual implications of what we're trying to do are much broader than just eligible providers in acute care hospitals.

Paul Egerman – eScription – CEO
Yes. It's a good point, Larry. In fact, it even ties into the statement Dr. Blumenthal made when we started the discussion because we really don't quite know. We're all little bit nervous about mission creep. We really don't quite know either legislatively or based on circumstances where this whole thing may be added in several years. And so to have flexibility to do different things could be very helpful.

David Blumenthal – Department of HHS – National Coordinator for Health IT
Yes. I would say that the policy committee—this is David Blumenthal—was constituted to have broad expertise and wisdom. And I think that its recommendations, thanks to your diligence and wisdom, have gained a lot of credibility. And I think that the Congress is feeling free to call on you to work harder and longer. I don't think that we're going to have a fixed mission over time. That's an observation, not an opinion.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO
Any other questions on 12? Paul, this is Paul Tang. May I ask a little bit on number three, which is differential certification? Let me just clarify. This is targeted towards the applicant, the applicant being the developer of software, that they wouldn't have to go back and re-certify their, let's say, stage one when they're doing stage two and three. Implicit under that is that everything is "backwards compatible" or that all the functionality is brought forward. Am I correct in that? Then the only way of sort of monitoring that is to invoke recommendation number two, which is re-certification if you're violating that. How are those related?

Paul Egerman – eScription – CEO
The requirements for number three is the first requirement is the test itself can't change, so there's a technicality there because if you've got … temporary program, and the permanent program for stage one has a different test, then you have to be tested again when you get to stage two. The test itself can't change. The other thing that can't change is the software version, however. If there's a version change in the software, then you also have to get tested again. So that forces us to make a definition of what that means, the software version.

What we were really looking for in this whole thing in this discussion is actually a somewhat confusing description of it in the second paragraph after the recommendation is that there are some vendors. You look at, for example, MetaTech, eClinicalWorks, these are vendors that have 2,000 or 3,000 users out in the field, and they have four or five different versions of their software in use. For those vendors, it's possible that what they might choose to do when they get to stage two is to simply add additional modules to the prior versions rather than try to push all of their customers to a new version. We were trying to find a simple way to do that, so we wouldn't clog up the entire testing process.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO
When you say modules though, it's a little – these terms are pretty vague, so let's say you're on version, the software version is four. It gets certified for stage one. Now you're two years later, and let's pretend at software version six. You're saying that people who have software versions four certainly don't have to get re-certified for stage one. But if you require version six to accomplish stage two, you would require users, customers to be on version six if you want to qualify for stage two. Is that correct?

Paul Egerman – eScription – CEO
I think it's right, but if I could slightly reword it. If a vendor responds to stage two by introducing version six of their system, yes, all of version six because it'd have to be retested. If, however, stage two, they're able to respond to it by saying it's still the same version four. We're just going to add some interoperability to do this one, or these two or three interfaces because CPOE and eligibility and that stuff didn't change, then they don't have to be retested.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO
For stage one functionality that is.

Paul Egerman – eScription – CEO
Against the stage one if the stage one … there are some things that might be the same between stage one and stage two, so eligibility checks and maybe CPOE. If there's no change in those between stage one and stage two, if they haven't changed the version number, they don't have to be retested again.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO
The second follow-on question then is, implicit in that is nothing, so nothing has been dropped. Let's say something was in the certified version, version four, and when you go to version six, at least to addressing stage one functionality or criteria. Nothing has been dropped in version six that was present in version four that was certified.

Carl Dvorak – Epic Systems – EVP
This is Carl. I wonder if we could solve that by where we say involving addition of substantial user feature or user functionality. We could refine that to say, as defined, as change involving an addition or removal of … user functionality. It might cover that use case you're talking about.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO
Right. Yes. We have to be … yes, we have to clear that they do not lose any functionality. They just have to test that and then they would … if that were an accurate reference.

Paul Egerman – eScription – CEO
Yes, that's a good suggestion, Carl. I appreciate that. I think that would respond to what you're asking for, Paul.

Larry Wolf – Kindred Healthcare – Senior Consulting Architect
I guess I'm hearing a second question in Paul's question. This is Larry. And that's, I'm a provider. I implemented version four that met stage one criteria. Now it's time for me to move to stage two, and the vendor was good in that it just had everything I need to do stage two is in version four, and the vendor has provided an additional model to fill in the hole for me. And so the question would be, can the vendor test version four of their software, and when they do submit for this subsequent testing for stage two, that they only need to be tested on the new criteria that are additional over stage one because they're not changing the version in providing me the functionality I need to go to stage two.

Paul Egerman – eScription – CEO
Good question. The way this is written, the answer is yes.

Larry Wolf – Kindred Healthcare – Senior Consulting Architect
I was restating that mostly so that Paul Tang could go, oh, that's what you guys were thinking.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO
I see. We haven't talked about that.

Paul Egerman – eScription – CEO
You were trying to stump me. Okay.

Larry Wolf – Kindred Healthcare – Senior Consulting Architect
I was not trying to stump you, Paul. I was trying to get Paul Tang to engage.

David Blumenthal – Department of HHS – National Coordinator for Health IT
This is David. I'm going to have to drop off the call, but I'm confident Paul will guide you well in my absence. Take care, everybody.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO
Thanks, David.

Paul Egerman – eScription – CEO
Thank you.

Deven McGraw - Center for Democracy & Technology – Director
Thank you.

Jodi Daniel – ONC – Director Office of Policy & Research
This is Jodi Daniel. Also, in the interest of time, I'm trying to figure out how we need to get some closure on this and look at the privacy and security one as well before we have to open it up for public comment.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO
Is it clear to other folks, other members of the committee what the intent is? Is it clear enough?

Deven McGraw - Center for Democracy & Technology – Director
Yes, I think so.

M
I think it's clear.

M
Yes.

M
Yes, I think it's clear.

W
Yes.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO
Any other comments about any of the other recommendations? Are we ready for a vote?

Tony Trenkle – CMS – Director of OESS
Paul, this is Tony. Just one clarification on the de-certification: This is fairly general, the recommendation, but obviously for us, it could have major operational ramifications, so I just don't know if there's any more clarity you want to put on the recommendation 2.0, but it's just something to think about.

Paul Egerman – eScription – CEO
What would you be looking for?

Tony Trenkle – CMS – Director of OESS
Well, I guess the question is the timing of de-certification, how will you define certain patterns of unsatisfactory surveillance, patient safety concerns emerge. There are a lot of general terms here that, I guess, are you leaving this up to ONC to define these? Because, as I say, if we're in the middle of a program, and somebody has got an EHR that all of a sudden gets de-certified, it creates some operational ramifications.

Paul Egerman – eScription – CEO
That's true.

Tony Trenkle – CMS – Director of OESS
…when people come in to test and things of that sort.

Paul Egerman – eScription – CEO
As we said, like in the final sentence of the recommendation, de-certification does not necessarily mean that the existing users will have their systems also decertified. It could mean that, but it does not necessarily mean that. For example, it depends on what the egregious situation is. Suppose the vendor had an allegation of bribery or something like that, they bribe the certification body. You might decertify that vendor for future marketing, but you might not pull the rug out from existing users. And so we just wanted to give the National Coordinator some authority. But as far as filling in the blank, we figured that the great legal staff at ONC would write stuff about due process and do this better.

Tony Trenkle – CMS – Director of OESS
Yes. That's….

Paul Egerman – eScription – CEO
We would just keep our view at a high level that there are some horrible things that could happen. We wanted the National Coordinator to pull the rug out from underneath somebody if that occurred.

Tony Trenkle – CMS – Director of OESS
Yes. Okay. That's fine. I mean, it's pretty generic, and if you feel that additional guidance isn't necessary, I can understand that, although it may be helpful at some point for the committee to take a look at that, as the program develops more.

Paul Egerman – eScription – CEO
Okay.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO
Thank you. Any other questions? All in favor of the letter, as proposed, with slight edits there?

Deven McGraw - Center for Democracy & Technology – Director
Yes.

W
Yes.

M
Yes.

M
Yes.

M
Yes.

M
Yes.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO
Any opposed? Any abstentions? Thank you. Deven, you want to talk about the privacy and security addition?

Deven McGraw - Center for Democracy & Technology – Director
Yes. Yes, thank you very much. Essentially, this set of recommendations is relatively short, and it deals only with one section of the rule, and that is the application of the privacy and security certification criteria, which were in the IFR, to EHR modules, which, as we all know that they're not complete EHRs, and they may perform certain functions, and so the notion of accomplishing all of the privacy and security criteria through modules that may or may not be consumer facing, that may or may not necessarily need to address all of these criteria presents an enormous challenge.

And so, essentially what the NPRM established was that the modules would need to meet all the criteria as a default, but then there were several exceptions enumerated. One is if the modules are sort of presented together for certification as a bundle, and this we talked about in our temporary certification letter, which the policy committee approved in the last go around, and I didn't realize we needed to incorporate those in here, and so we will do so. Generally we just raise the question there about where you've got a bundle, but the NPRM raises a possibility of an exception where there's one particular service that's provided offsite. It was very confusing, and we asked for further clarification on that one.

The other two exceptions you can see in this letter. One is where it's technically infeasible for the module to be tested, and the third is where the module is really only designed to perform a specific privacy and security capability. Essentially what we're asking for here is for HHS to ideally or ONC, rather, to provide some clarification about what they mean by technical infeasibility just so that both industry and the public have some examples of circumstances that qualify for technical infeasibility.

Then last set of recommendations really go to again this concept that you're sort of cobbling together a collection of modules and maybe there would be circumstances in fact where you don't necessarily want all of the modules to meet all of the criteria because, if they do so, not necessarily in a consistent or interoperable way, you may not end up at the end of the day with a system that actually provides the type of security that the certification criteria envisions because essentially the component parts don't work well

together. But, of course, we know we don't have good standards for interoperability yet, so we cannot ask the certification program to test for the interoperability of these various security functionalities that are presented in the module.

So the main piece of the recommendation is to require for modular certification that the module vendors provide a lot of information about the module: how it works, what's the assumed environment? What interfaces are necessary to other products or services? The conditions under which they're functional and when they're not, what criteria are actually accomplished by the—and I see that there's a typo here. I'm not trying to genderize EHRs. Spell check fixing my typo for me. Which of the criteria are accomplished and which are not? And if in fact the product is designed to perform a specific capability, some specification of interface … these services are going to be provided to other modules. Then that, of course, is consistent with what the certification and adoption workgroup has said, would then be on the label. We're essentially putting more in, asking for more information to be put out there for potential purchasers who are going with the module route so that they know what they're getting when they buy it.

I'll stop there, and thanks to all who have let me know about the typos. I very much appreciate that, and they will be fixed.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO
Thanks, Deven. Any comments or questions for her? Are people in agreement with the letter then? Are we ready to vote?

Deven McGraw - Center for Democracy & Technology – Director
I am.

W
I'm fine.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO
Okay. All in favor?

W
Yes.

W
Yes.

M
Aye.

W
Yes.

M
Yes.

M
Aye.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO

Any opposed? Any abstention? I certainly want to thank both of the workgroups, the certification and adoption workgroup that keeps coming forward with all these important recommendations, and the privacy and security … still working on this foundational aspect of the program and its many ramifications in the various NPRMs and IFRs. Thank you to the group. We'll be opening up to public comments now. While we're doing that, any other comments from the group or agenda items?

Operator
We have a comment from John Travis.

John Travis – Cerner – Sen. Dir. & Solution Strategist – Regulatory Compliance
Thank you. This is John Travis with Cerner. I guess a question on the one recommendation in the first letter about not having to retest EHRs or EHR modules, stage one to stage two for criteria that doesn't change, provided it's the same version. Really kind of two questions: One, does it fit within that recommendation if there's an aspect of the software that doesn't change version-to-version that's supported meaningful use for an objective? So if the CPOE module was not subject to any enhancement version-to-version, would the CPOE module need to be retested with a new version in a future stage? That's quite common, so not only might we make software backward compatible, we might only introduce new software with a new version and not touch something that was the basis of certification before.

The second part of that is kind of asking that question in reverse, and that is whether or not there's an inheritance of an existing certification for future versions where the certification criteria doesn't change and those new versions are introduced during a stage of meaningful use? It kind of is like, I think, a recommendation you made in the temporary letter where you said, for minimum standards, a user could upgrade without jeopardizing the certification status of their system. This is more from the vendor perspective, if that makes sense.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO
Paul, did you want to--?

Paul Egerman – eScription – CEO
Do you want me to answer that? I'll do my best. The best I could do is the answer to the second part is, you have to remember certification is like a snapshot in time.

John Travis – Cerner – Sen. Dir. & Solution Strategist – Regulatory Compliance
Right.

Paul Egerman – eScription – CEO
And the recommendation that we're making is that certification also says what version got certified. That does stop a vendor from selling other versions. And … label that says you have version four, and you got certified for version three. You have a version label that says version three on it. If that works, fine, that works. It depends on what the certification body does when it does its surveillance. It certainly doesn't prevent you from doing what people in the industry normally call a point release where you've got some operational issue. That's my answer to your issue about….

I think the second part of your question, I'm sorry. I didn't understand the first part of the question.

John Travis – Cerner – Sen. Dir. & Solution Strategist – Regulatory Compliance
The first one, it's not unlike that, and you may have actually answered it. But let's say CPOE is done, so to speak, and was certified on version two. CPOE was not touched in a newer version of the software. It's completely unchanged. We're now to stage two. So stage one, it was certified on version two for

CPOE. In stage two, CPOE is, let's say, carry over without changes to the certification criteria from stage one. The software has not changed, but a new version is being certified by the vendor because there's a new interoperability requirement that's supported by that new release. Would that CPOE module have to be retested for version four, although the basis of code had not changed?

Paul Egerman – eScription – CEO
The issue there, it's an interesting question, a little bit complicated. But the issue there is if you're installing a complete EHR, which probably is the case with Cerner, and if you've really changed your version number, then our recommendation says you've got retest everything. If you are installing a complete EHR, and you have not changed your version number, all you did was put on some sort of interface module or something, then our recommendation is you do not need to retest.

If you're certifying a module, then it gets a lot easier. If you're just doing a module that does CPOE, then it's actually very easy. There's no test, no change in test criteria, and there's no change in the code base….

John Travis – Cerner – Sen. Dir. & Solution Strategist – Regulatory Compliance
You'd only be submitting the modules for the new requirement presumably.

Paul Egerman – eScription – CEO
Pardon me?

John Travis – Cerner – Sen. Dir. & Solution Strategist – Regulatory Compliance
You might only be submitting the module….

Paul Egerman – eScription – CEO
That's correct.

John Travis – Cerner – Sen. Dir. & Solution Strategist – Regulatory Compliance
…requirement where it was relevant.

Paul Egerman – eScription – CEO
That's correct.

John Travis – Cerner – Sen. Dir. & Solution Strategist – Regulatory Compliance
No, that makes sense. CCHIT's current practice is pretty much a full new test when you have a new version, and we're used to that, but I was just curious.

Paul Egerman – eScription – CEO
Okay.

John Travis – Cerner – Sen. Dir. & Solution Strategist – Regulatory Compliance
Thank you.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO
Any other…?

Paul Egerman – eScription – CEO
Arguably, this is our recommendation. What actually comes out the other side, we don't know. There's still time for Cerner to make its recommendations too if you like this or you have an alternate suggestion.

John Travis – Cerner – Sen. Dir. & Solution Strategist – Regulatory Compliance
Yes, and we certainly will.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO
Any other public comments?

Operator
Yes, we have another public comment from Cindy….

Shandra
Hello. I'm Shandra from U.S. Health Circuit. My question is regarding the definition of the term version. We are basically a Web based system, Web portal, so we make frequent updates … conventional deployment based systems, so how would the term version apply to us?

Paul Egerman – eScription – CEO
That's a great question. Actually, the hottest part of that entire recommendation is the definition of version. You raise a great question. In one sense, my answer would be, well, it doesn't really change the definition. The question is going to be, is there substantial user functionality, or is there a change in technology? Either one of those, in my opinion, creates a new version. But it's hard to know what substantial user functionality is. And my suggestion to you, since you raised a good question, is you submit your own letter of recommendation on this point to ONC with a definition that will fit for a Web based system because it's a good question.

W
Thank you.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO
Any other questions?

Operator
There are no other comments waiting.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO
Thanks again to the committee for assembling on such short notice and for all the great work that goes on in the workgroup, and until next time, in a week or two, I guess. Thanks a lot.

W
Thank you.

W
Thanks.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO
Bye.

Paul Egerman – eScription – CEO
Thank you.

W

Good-bye.

M
Thank you. Bye.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO
Bye.